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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/604,203	07/01/2003	Muhammed Majeed		1202

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EXAMINER

PRATS, FRANCISCO CHANDLER

ART UNIT PAPER NUMBER

1651

DATE MAILED: 12/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/604,203

Applicant(s)

MAJEED ET AL.

Examiner

Francisco C. Prats

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-14 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____ |

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DETAILED ACTION

An examination of this application reveals that applicant is unfamiliar with patent prosecution procedure. While an inventor may prosecute the application, lack of skill in this field usually acts as a liability in affording the maximum protection for the invention disclosed. Applicant is advised to secure the services of a registered patent attorney or agent to prosecute the application, since the value of a patent is largely dependent upon skilled preparation and prosecution. The Office cannot aid in selecting an attorney or agent.

A listing of registered patent attorneys and agents is available on the USPTO Internet web site <http://www.uspto.gov> in the Site Index under "Attorney and Agent Roster." Applicants may also obtain a list of registered patent attorneys and agents located in their area by writing to the Mail Stop OED, Director of the U. S. Patent and Trademark Office, PO Box 1450, Alexandria, VA 22313-1450

Claims 1-14 are presented for examination.

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Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-14 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Specifically, the claims recite the production of the policosanol-type alcohol mixture from any and all "plant or animal sources," using any and all enzymes in the purification step. Thus, the claims encompass the use of numerous potential products as starting materials, such as animal byproducts, plant byproducts, and other carbohydrate-containing materials such as sewage, for which no written description has been provided. Moreover, the sole example of using a sugarcane pressmud starting material with a lipase as the hydrolytic enzyme does not provide a representative sample of the starting materials and hydrolytic enzymes encompassed by

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the claims, given the huge variation in physical, structural, and chemical properties encompassed by the current broad claim language. Because the claims encompass a multitude of starting materials and hydrolytic enzymes neither contemplated nor disclosed by the as-filed disclosure, it is clear that applicant was not in possession of the full scope of the claimed subject matter at the time of filing.

Claims 1-14 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the use of lipase in the treatment of the policosan-ol-containing starting materials disclosed in the specification (sugarcane, bees wax, rice bran) to produce the policosan-ol-type alcohol mixture, does not reasonably provide enablement for the production of the policosan-ol-type alcohol mixture from any and all "plant or animal sources," using any and all enzymes in the purification step. Specifically, as discussed above, the claims encompass the use of numerous potential products as starting materials, such as animal byproducts, plant byproducts, and other carbohydrate-containing materials such as sewage, for which no disclosure has been provided. Moreover, the sole example of using a sugarcane pressmud starting material with a lipase as the hydrolytic enzyme does not provide a

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representative sample of the starting materials and hydrolytic enzymes encompassed by the claims, given the huge variation in physical, structural, and chemical properties encompassed by the current broad claim language.

Given the huge variation in physical, structural, and chemical properties for starting materials encompassed by the current broad claim language, the skilled artisan would not expect to be able to apply the disclosed techniques to any and all starting materials encompassed by the current claim language. Thus, with the exception of the policosanol-containing starting materials explicitly disclosed in the specification (sugarcane, bees wax, rice bran), and in view of the lack of any specific guidance with respect to the use and handling of any other starting materials encompassed by the claims, the skilled artisan would expect to have to undertake a trial and error process to determine which of the multitude of substrates encompassed by the claims would be amenable to the techniques disclosed in the instant application, and would further have to determine through trial and error experimentation, without guidance from the specification, how to adopt the techniques disclosed in the instant application to the widely varying starting materials presently encompassed by the

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claims. Such a trial and error process clearly amounts to undue experimentation.

Undue experimentation would be required to practice the invention as claimed due to the quantity of experimentation necessary; limited amount of guidance and limited number of working examples in the specification; nature of the invention; state of the prior art; relative skill level of those in the art; predictability or unpredictability in the art; and breadth of the claims. *In re Wands*, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claim(s) are narrative in form and replete with indefinite and functional or operational language. Note the format of the claims in the patent(s) cited.

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Specifically, claims 2-14 are not drafted so as to properly depend from claim 1. In claim 2, the recitation "The claim in 1" is improper. In claim 4, "the said claim in 1" makes no sense. In claims 5-15, the recitation of properties of the product by the process fails to clearly limit the process in independent claim 1. For example, claim 5 recites "the said alkanols in claim 1". However claim 1 recites a "method" of preparing alkanols, not the alkanols themselves.

Also, in claim 1, the recitation "novel" is superfluous, since patented claims are by definition novel.

The term "economically viable" in claim 1 is indefinite because the criteria for that term are entirely subjective. A process one practitioner considers to be viable economically would not necessarily be considered the same way by another practitioner.

The recitation "small percentage" in claim 1 is indefinite because it is not clear how small the percentage must be.

The recitation "purification by enzyme" in claim 1 is indefinite because it is not clear what actions must be performed using the enzyme.

Claim 2 is indefinite because it is not clear whether the subject matter described by the term "especially" is intended to be part of the claim or not. Also, it is not clear which part

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of the claim is intended to be "collectively" known as policosanol, nor is it clear who must know this.

The recitation "preferably" in the claims is indefinite because it is not clear when the preference ("preferably . . . more preferably") is to be exercised.

Also, claims 5-14 are confusing in that it is not clear what actions, if any, are required by these claims. It appears that these claims merely recite intended uses of the product made by the process recited in claims 1 and 5.

No claims are allowed. However, claims directed to a process for the production of a composition comprising 70 to 95% C₂₄-C₃₆ alkanols, said process comprising the steps of extracting a substrate selected from the group consisting of sugarcane, beeswax, or rice bran, with supercritical carbon dioxide, in the presence of a lipase enzyme, are considered free of the prior art. Specifically, although the prior art discloses generally that lipase-catalyzed extractions of lipid-containing plant or animal materials in supercritical carbon dioxide was known (see e.g. Jackson et al (JAOCS 73(3):353-356 (1996)); see also Gunnlaugsdottir et al (JAOCS 74(11):1483-1494 (1997) (two articles)), no prior art suggests obtaining the specific

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composition containing comprising 70 to 95% C₂₄-C₃₆ alkanols using the claimed method steps.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Francisco C. Prats whose telephone number is 571-272-0921. The examiner can normally be reached on Monday through Friday, with alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read 'F. Prats', with a long horizontal stroke extending to the right.

Francisco C. Prats
Primary Examiner
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FCP